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A Retrospective, Multicenter, Observational Real World Post Market Clinical Follow Up Study to Evaluate Acute Safety and Device Procedural Success of ADVAMRYL (Poliglecaprone 25) Surgical Suture: ADVAMRYL PMCF Study

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Abstract
In this real-world experience Post-Marketing Clinical Follow-up study conducted in accordance with EU MDR 2017/745 in 70 subjects from >60 surgical centers across various surgical specialties, ADVAMRYL (Poliglecaprone 25) monofilament, synthetic absorbable sterile surgical sutures demonstrated excellent suture, needle, and overall performance. No wound complications or adverse events were reported in this study during the follow-up period of 3 months, and there were no reports of prolonged or repeat hospitalization. ADVAMRYL (Poliglecaprone 25) sutures are a safe and effective option for a very wide variety of surgical procedures in a diverse population.

Keywords: Poliglecaprone 25, Monofilament, Synthetic absorbable suture, Obstetrics and Gynecology surgery.

INTRODUCTION

Sutures are sterile surgical threads used to approximate and/or ligate tissues. They are essential for wound closure in a variety of surgical procedures, including general surgery, gynecology, ophthalmology, and cardiovascular surgery. Sutures are available in a wide range of materials, including natural (e.g., catgut, silk) and synthetic (e.g., nylon, polyester, polyglactin 910). [1]

Synthetic absorbable sutures are available as braided constructions or as monofilaments. Braided absorbable sutures are made either from 90:10 poly (glycolide-co-L (-)-lactide. There are, however, some concerns with braided sutures that relate to tissue drag and the trauma this may cause, as well as the possible potentiation of infection through the interstices of the braid structure.

Absorbable monofilaments, such as the monofilament sutures derived from p-dioxanone homopolymer, or a copolymer of trimethylene carbonate and glycolide, eliminate many of these concerns, but generally monofilaments do not handle as well as braids.

Monofilament synthetic absorbable surgical sutures prepared from a copolymer of glycolide and epsilon-caprolactone, such as ADVAMRYL (poliglecaprone 25), have been extensively studied for their mechanical and handling properties.

Poliglecaprone 25 synthetic, monofilament absorbable sutures, based on segmented block copolymers of epsilon-caprolactone and glycolide display excellent handling properties, minimal resistance during passage through tissue and excellent tensile properties. These sutures provide an in vivo breaking strength retention of approximately 20-30% after 2 weeks, considered by many to be the critical wound healing period. Absorption data on these sutures show that absorption is complete between the 91st and 119th days of implantation, with slight or minimal tissue reaction, which aligns with the critical wound healing period. [2]

Comparative studies have shown that glycolide-epsilon-caprolactone copolymer sutures exhibit high knot failure load, indicating good mechanical strength and reliability in maintaining tissue approximation under stress.[3] Additionally, these sutures demonstrate superior wound healing outcomes compared to multifilament sutures, likely due to reduced bacterial colonization and tissue reaction.[4]

1. **Tissue Reaction:** Although monofilament sutures generally provoke less tissue reaction compared to multifilament sutures, absorbable sutures, including those made from glycolide and epsilon-caprolactone, can still cause some degree of tissue inflammation. This reaction can potentially affect wound healing.[4]
2. **Bacterial Colonization:** Monofilament sutures are less prone to bacterial colonization compared to multifilament sutures, which reduces the risk of infection. However, they are not completely immune to bacterial adherence, which can still occur, particularly in contaminated or infected surgical fields.[4]
3. **Degradation and Absorption:** The degradation process of these sutures involves hydrolysis, which can sometimes lead to premature loss of tensile strength before adequate wound healing has occurred. This is particularly relevant in tissues that require prolonged support.[5]
4. **Suture-Related Discomfort:** Some patients may experience discomfort related to the presence of the suture material, although this is generally less common with monofilament sutures compared to multifilament options.[4]
5. **Wound Dehiscence:** Although rare, there is a potential risk for wound dehiscence if the suture loses tensile strength too rapidly or if it is not appropriately selected for the tissue type and surgical procedure.[6]

In summary, while monofilament synthetic absorbable sutures made from glycolide and epsilon-caprolactone are associated with fewer complications compared to multifilament sutures, they are not without risks, including tissue reaction, bacterial colonization, premature degradation, suture-related discomfort, and potential wound dehiscence.

In summary, the current level of evidence supports the use of monofilament synthetic absorbable sutures made from glycolide and epsilon-caprolactone copolymers for their favourable handling, mechanical properties, and biocompatibility. These characteristics make them suitable for various surgical applications, particularly where minimal tissue reaction and reliable tensile strength are required.

Advanced MedTech Solutions (AMS) (https://www.amsltd.com/products/advamryl/) a monofilament synthetic absorbable suture called ADVAMRYL that is composed of a copolymer made from glycolide

and ε-caprolactone.

ADVAMRYL suture is available in both dyed and undyed form. ADVAMRYL suture complies with United States Pharmacopeia requirement for "Absorbable Surgical Suture" and the European Pharmacopoeia for "Sterile Synthetic Absorbable Monofilament Sutures".

ADVAMRYL (Poliglecaprone 25) suture is indicated for use in general soft tissue approximation and/or ligation, but not for use in ophthalmic surgery, microsurgery, cardiovascular and neurological tissues.

The absorption process begins at the suture surface and progresses inward. The progressive loss of tensile strength and eventual absorption of ADVAMRYL occurs by means of hydrolysis. Absorption begins as a loss of tensile strength followed by a loss of mass. The suture is designed to maintain 60% of its tensile strength for 7 days, 40% for 14 days, and All of the original tensile strength is lost by 21 days post implantation. The rate of absorption depends on several factors, including the suture diameter, the type of tissue, and the patient's individual metabolism. ADVAMRYL (Poliglecaprone 25) sutures are completely absorbed within 90 days.

Advamryl (poliglecaprone 25) synthetic, monofilament absorbable sutures have demonstrated specific benefits in certain patient populations due to their favourable handling characteristics, minimal tissue reaction, and reliable tensile strength.

1. Patients Undergoing Uvulopalatopharyngeal Surgery: According to a randomized trial, Monocryl sutures exhibited optimal handling characteristics and a two-stage degradation process, making them particularly suitable for uvulopalatopharyngeal surgery. This is crucial in the complex oral environment where constant saliva presence and microbial accumulation are concerns.[7]
2. Patients Undergoing Dentoalveolar Surgery: Poliglecaprone 25 sutures have shown superior wound healing and reduced bacterial colonization compared to multifilament sutures in dentoalveolar surgery. This is significant for patients undergoing procedures such as the extraction of impacted third molars, where minimizing infection risk and promoting efficient wound healing are critical.[4]
3. General Surgical Patients: Poliglecaprone 25 sutures are beneficial in general surgical applications where minimal tissue reaction and reliable tensile strength are required. Their monofilament nature reduces the risk of bacterial colonization, which is advantageous in reducing postoperative infections and promoting better wound healing outcomes. [4,8]

In summary, Poliglecaprone 25 sutures are particularly advantageous for patients undergoing uvulopalatopharyngeal and dentoalveolar surgeries, as well as in general surgical contexts where minimizing tissue reaction and infection risk is paramount.

ADVAMRYL (poliglecaprone 25) sutures have been used widely in various types of surgical procedures. We are not aware of any systematic study done till date in an Indian population to determine safety and performance of the Poliglecaprone 25 suture in real world scenario.

MATERIALS AND METHODS

Study Design and Conduct

A real-world experience study was designed as 'A Multicenter, Real World Retrospective Post Market Clinical Follow-up Study to Evaluate Acute Safety and Device Procedural Success of Poliglecaprone 25 (ADVAMRYL) Surgical Suture.' (ADVAMRYL PMCF STUDY)

A combination of heterogeneous data from different centers was collected to reinforce analyses and strengthen clinical outcomes.

ETHICS COMMITTEE APPROVAL

Institutional Ethics Committee approval was obtained from the ACEAS Independent Ethics Committee, Ahmedabad -380015 after submitting the clinical study documents (Product Information, PMCF protocol (AMS/ADVAMRYL/2021 Ver. 02), CRF, etc.). The informed consent was waived on account of this being a retrospective study. Since ADVAMRYL is a CE-certified device, the study was conducted as per the regulatory guidelines of EU MDR 2017/745. The study done as per the ICH – GCP, ICMR guidelines and New Drugs & Clinical Trials Rules 2019 (India).

ELIGIBILITY AND INCLUSION

The study was planned to include 156 subjects, we could not reach these numbers due to various reasons like less than expected sales, instability in our organization, etc. PMCF data of 70 Subjects was collected from January 2023 to December 2023 for which analysis has been done.

All the subjects enrolled met the inclusion criteria in the study were included in this retrospective study:

Inclusion criteria

Patients who have been treated with ADVAMRYL (Poliglecaprone 25) suture.

Exclusion criteria

As this is retrospective review of the data, there are no formal exclusion criteria for the study.

Outcome measures/ endpoints

Primary Endpoint

- Number of Subjects presenting with wound complications [Time Frame: 03 months].
- Any wound disruption, wound dehiscence, fluid accumulation, and separation (Surgical Site Infection (SSI), Hematoma, Separation, Seroma, etc.).

Secondary Endpoint

- Mean Operation Time in minutes [Time Frame: Intraoperative]
- Total procedure time [Time Frame: Intraoperative]
- Any Device Malfunction or Device Failure [Time Frame: Intra and Postoperative]
- Any Device Malfunction or Device Failure related to the use of ADVAMRYL (based on the Investigator's Investigation for events not limited to Failure to perform or any other Malfunction when used in compliance with the Instructions for Use.)
- Length of Hospital Stay in days [Time Frame: From Postoperative through 03 month]
- Number of patients requiring Reoperation or Additional Surgical procedure [Time Frame: From Postoperative through 03 months]
- Number of patients presenting with Adverse Events related to the use of ADVAMRYL surgical suture [Time Frame: From Postoperative through 03 months] (Any Adverse Events related to the use of ADVAMRYL were based on the Investigator's Investigation.)
- Number of patients requiring Additional Surgical procedure resulting from Device malfunction, Device failure or any Adverse events [Time Frame: From Postoperative through 03 months]

All comer Subjects with ADVAMRYL of any size or length were included in study and follow up for 3 months as per PMCF plan.

RESULTS AND DISCUSSION

Study Report

Data of 70 subjects was collected and analysed from different Surgeons and Hospitals from January 2023 till December 2023.

STUDY POPULATION: AGE, GENDER, MEDICAL AND TREATMENT HISTORY BASELINE CHARCTERISTICS

For Baseline Characteristics, the following attributes were studied.

1. Subjects' Age
2. Subjects' Gender
3. Medical History

Mean Age of the Study population age was 38.8 years with lowest age of 24 and highest age of 65, describe categories with 33 % of males and 67% of Females. No Subjects had medical history of diabetes mellitus, and hypertension.

Table 1: Gender distribution of the subjects

Gender	70 Subjects
Female	67%
Male	33%

Figure 1: Gender distribution of the subjects

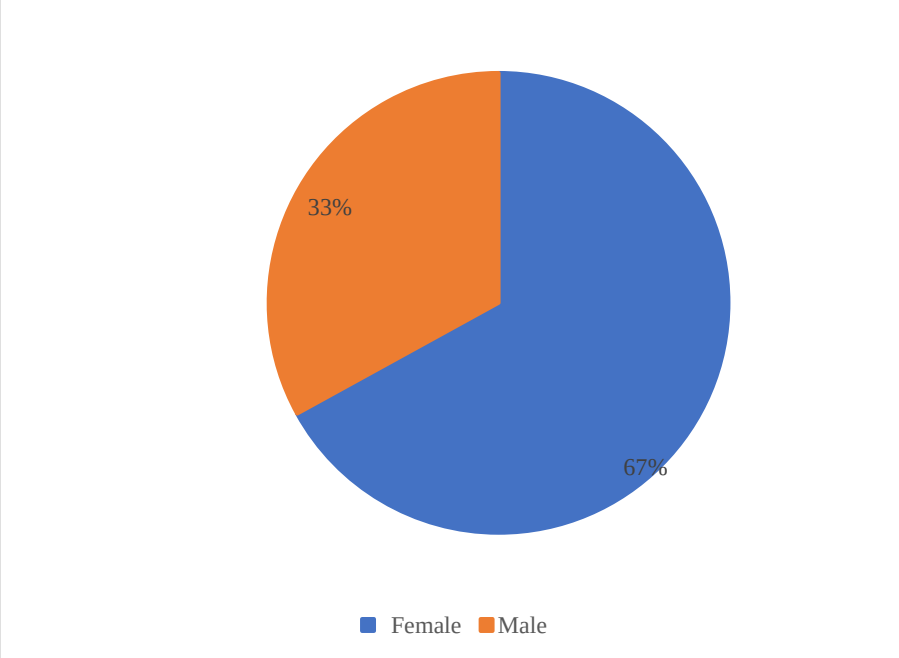


Table 2: Age categories

Age categories	70 Subjects
Between 18 and 65 years	100%
≥ 65 years	0%

Figure 2: Age Categories

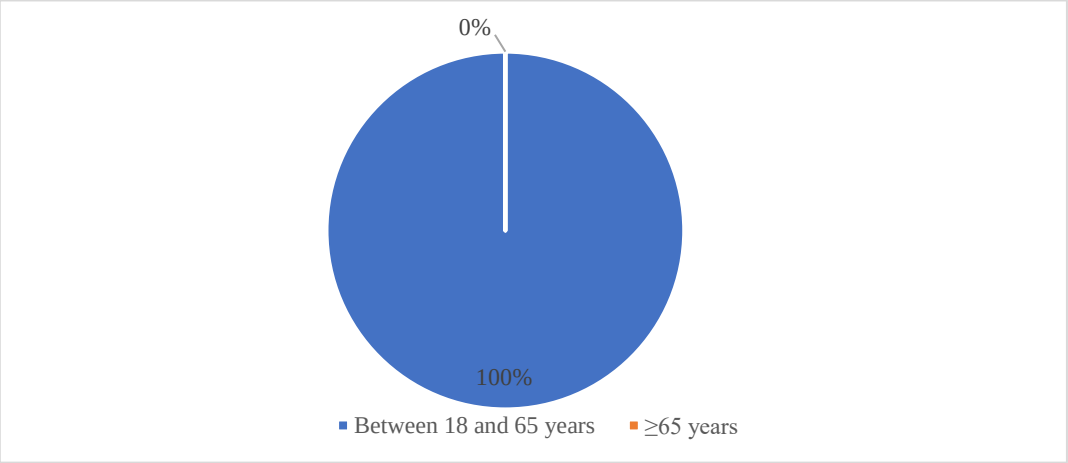


Table 3: Medical history of the subjects

Medical history	70 Subjects	Percentage
None	70	100%

OPERATIVE DATA ANALYSIS

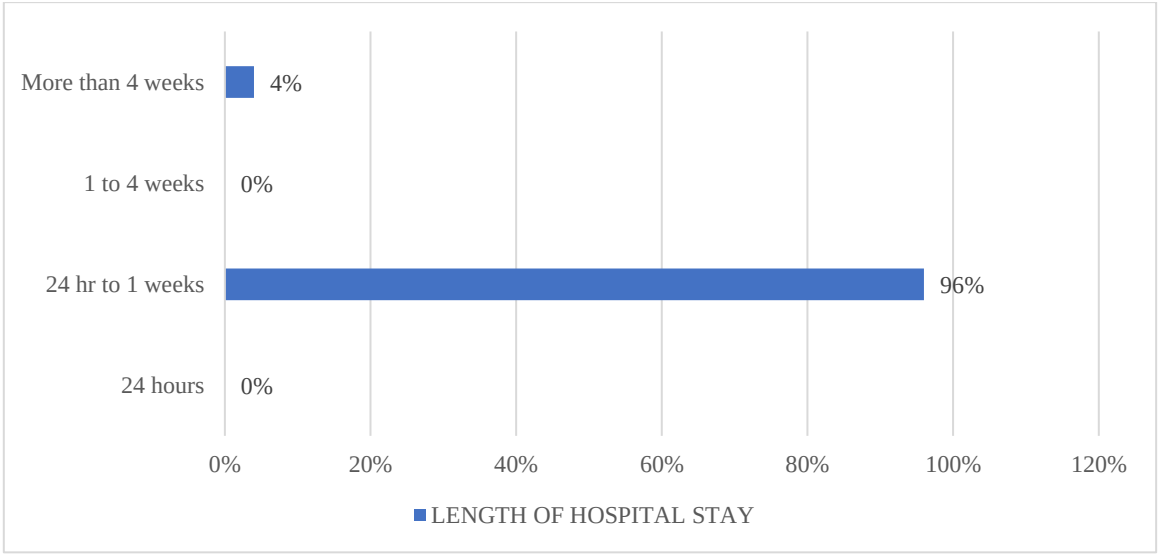
LENGTH OF HOSPITAL STAY

In total, the length of hospital stays of 96% of the subjects was 24 hours to 1 week, 4% of more than 4 weeks.

Table 4: Length of hospital stay

Length of Hospital Stay	70 Subjects	Percentage
24 hours to 1 week	67	96%
1 to 4 weeks	0	0%
More than 4 weeks	3	4%
24 hours	0	0%

Figure 3: Length of hospital stay



PATIENT BASELINE INFORMATION

CLINICAL PRESENTATION ON THE DAY 0

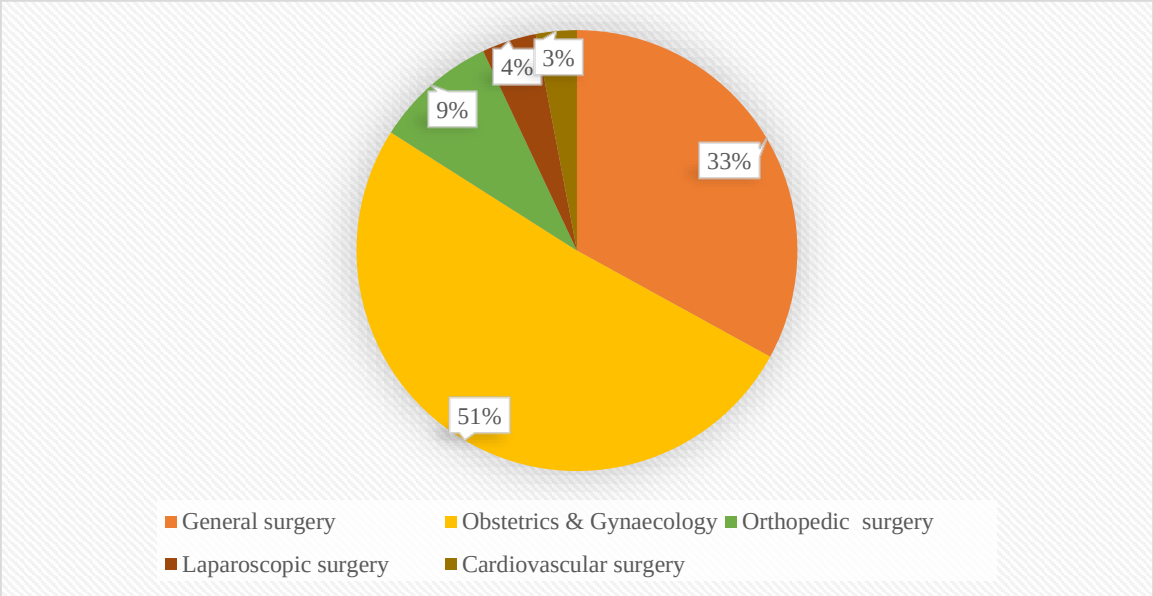
Of the 70 subjects, 33% of the Subjects underwent procedures in General Surgery, 9% in Orthopaedic Surgery, 51% in Ob and Gyn Surgery, 4% in laparoscopic surgery and 3% in Cardiovascular surgery.

STATICAL ANALYSIS: SURGERY

Table 5: List of surgical procedure where ADVAMRYL was used.

Surgery name	Number of subjects (70 subjects)	Percentage
General Surgery	23	33%
Orthopaedic Surgery	6	9%
Obstetrics And Gynaecology Surgery	36	51%
Laparoscopic Surgery	3	4%
Cardiovascular surgery (soft tissue closure)	2	3%

Figure 4: Percentage of procedures in various Surgical Categories



STATISTICAL ANALYSIS: STATE

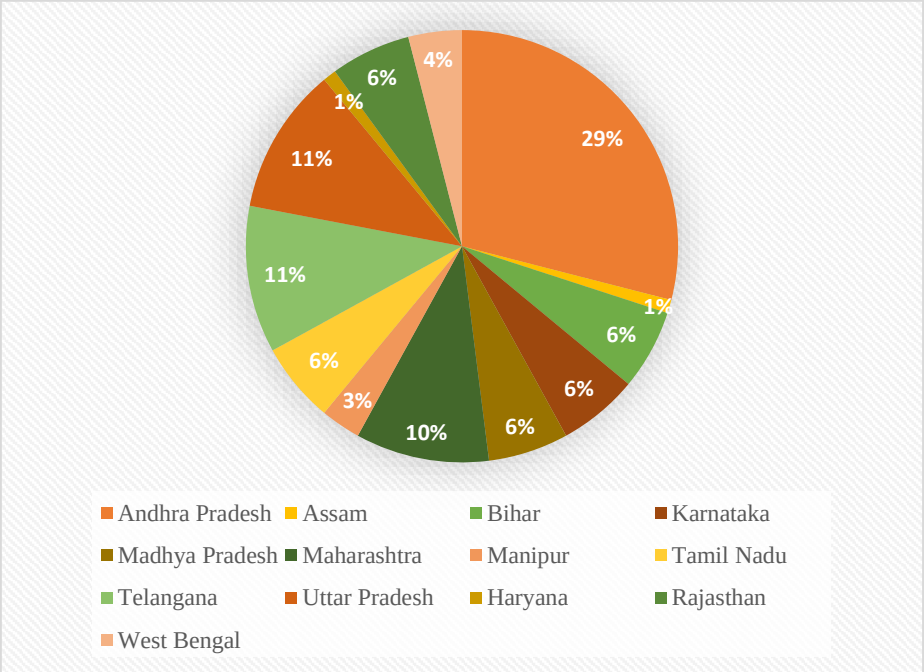
In total, 29% of the Subjects from Andra Pradesh, 11% from Telangana, 11% from Uttar Pradesh, 10% from Maharashtra, 6% from Tamil Nadu, 6% from Bihar, 6% from Madhya Pradesh, 6% from Karnataka, 6% from Rajasthan, 4% from West Bengal, 3% from Manipur, 1% from Assam and 1% from Haryana.

Table 6: Number of subjects from different states

State	Number of Subjects (70 Subjects)	Percentage
Andhra Pradesh	20	29%
Assam	1	1%
Bihar	4	6%

Karnataka	4	6%
Madhya Pradesh	4	6%
Maharashtra	7	10%
Manipur	2	3%
Tamil Nadu	4	6%
Telangana	8	11%
Uttar Pradesh	8	11%
Haryana	1	1%
Rajasthan	4	6%
West Bengal	3	4%

Figure 5: Number of Subjects from different states



ADVAMRYL HANDLING CHARACTERISTICS

SUTURE PERFORMANCE

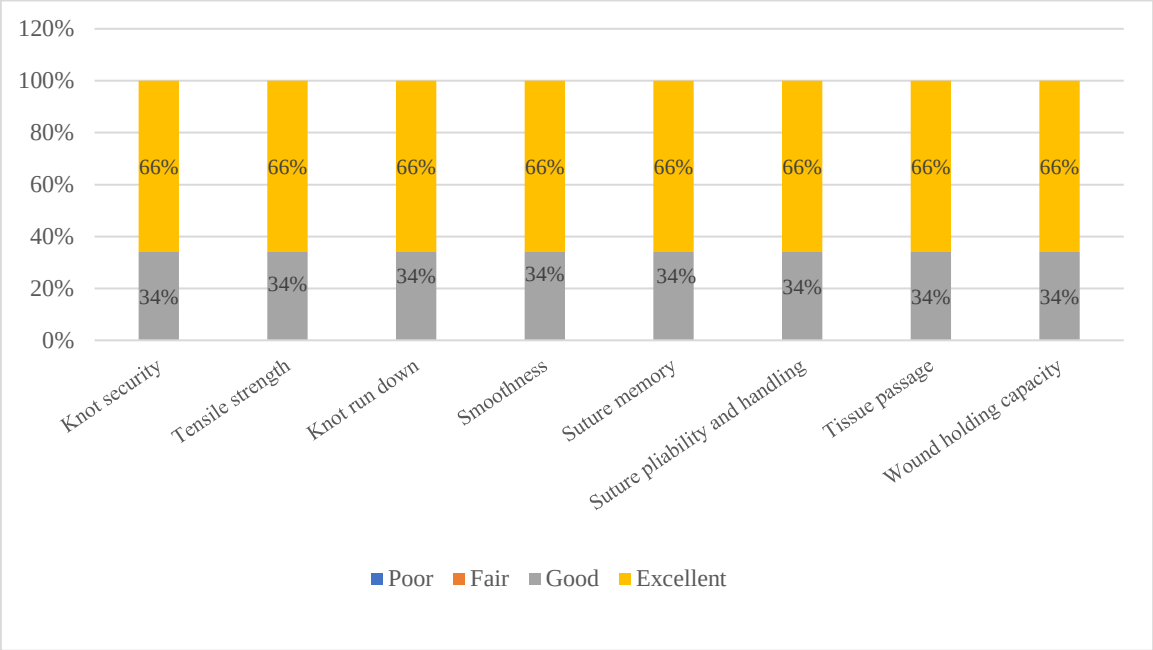
For Suture Performance, Knot Security, Tensile Strength, Knot Run Down, Smoothness, Suture Memory, Suture Pliability and Handling, Tissue Passage, and Wound Holding Capacity attributes were studied.

Table 7: Rating of Suture Performance attributes

70 Number of Subjects analyzed				
Rating Category	**Poor**	**Fair**	**Good**	**Excellent**
Knot security	0%	0%	34%	66%
Tensile strength	0%	0%	34%	66%
Knot run down	0%	0%	34%	66%
Smoothness	0%	0%	34%	66%
Suture memory	0%	0%	34%	66%

70 Number of Subjects analyzed				
Rating Category	**Poor**	**Fair**	**Good**	**Excellent**
Suture pliability and handling	0%	0%	34%	66%
Tissue passage	0%	0%	34%	66%
Wound holding capacity	0%	0%	34%	66%

Figure 6:Suture Performance attributes



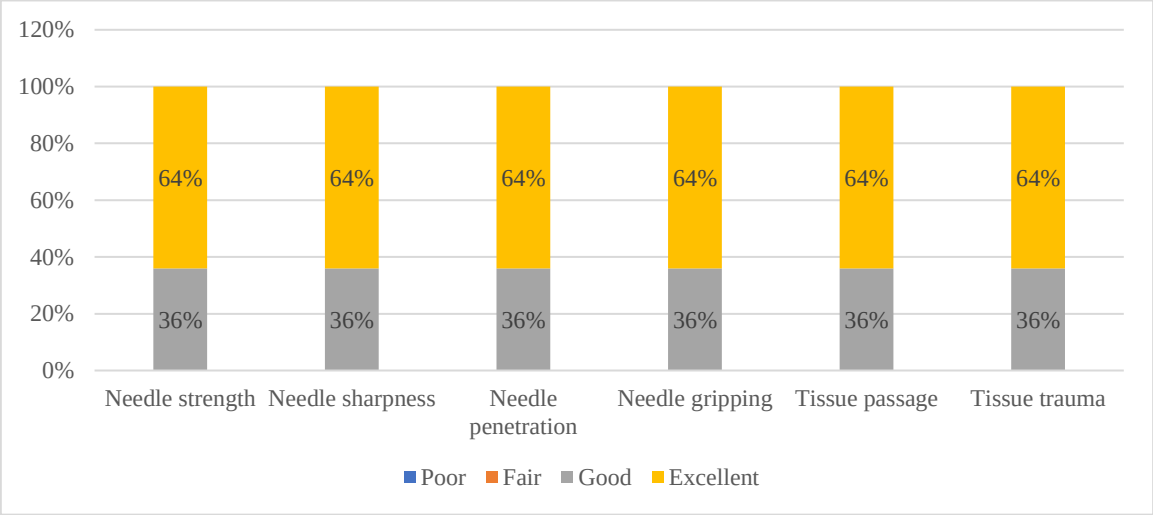
NEEDLE PERFORMANCE

For needle performance like Needle strength, Needle sharpness, Needle penetration, Needle gripping, Tissue passage, and Tissue trauma were studied.

Table 8: Rating of Needle Performance attributes

70 Number of Subjects analyzed				
Rating Category	**Poor**	**Fair**	**Good**	**Excellent**
Needle strength	0%	0%	36%	64%
Needle sharpness	0%	0%	36%	64%
Needle penetration	0%	0%	36%	64%
Needle gripping	0%	0%	36%	64%
Tissue passage	0%	0%	36%	64%
Tissue trauma	0%	0%	36%	64%

Figure 7: Needle performance attributes



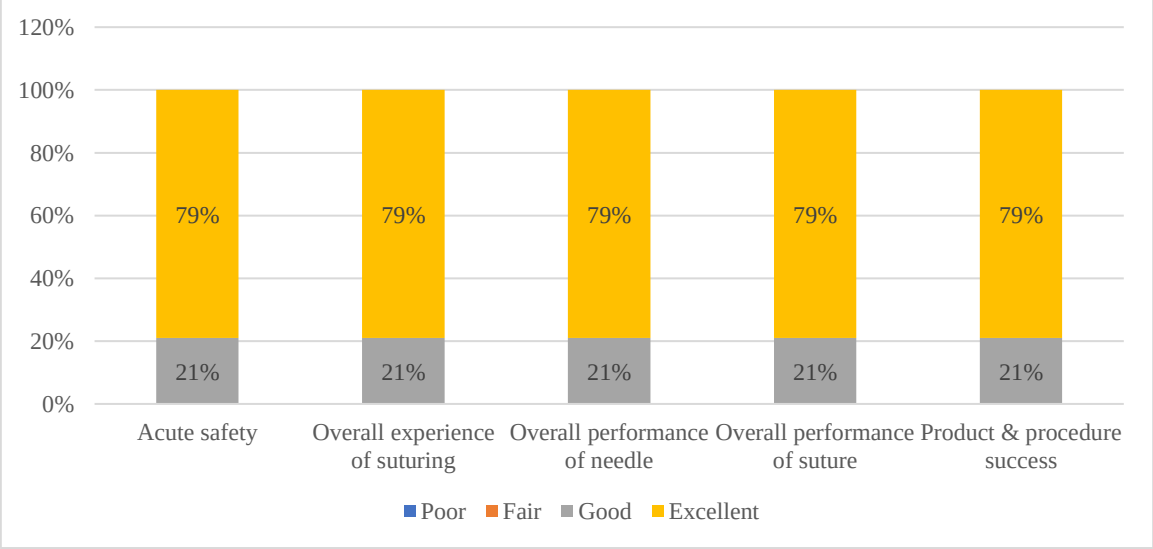
OVERALL PERFORMANCE

For Overall Performance of The Product, Acute Safety, Overall Experience of Suturing, Overall Performance of Needle, Overall Performance of Suture, Product & Procedure Success attributes were studied.

Table 9: Rating of Overall performance of the product

70 Number of Subjects analyzed				
Rating Category	**Poor**	**Fair**	**Good**	**Excellent**
Acute safety	0%	0%	21%	79%
Overall experience of suturing	0%	0%	21%	79%
Overall performance of needle	0%	0%	21%	79%
Overall performance of suture	0%	0%	21%	79%
Product & procedure success	0%	0%	21%	79%

Figure 8: Overall performance



CLINICAL PRESENTATION FOR THREE MONTHS FOLLOW UP DATA

At 3 months follow up, the following attributes were studied.

1. Tissue approximation
2. Wound complications like wound disruption, wound dehiscence, fluid accumulation, separation.
3. Suture Absorption time.
4. Details of adverse events/ serious adverse events

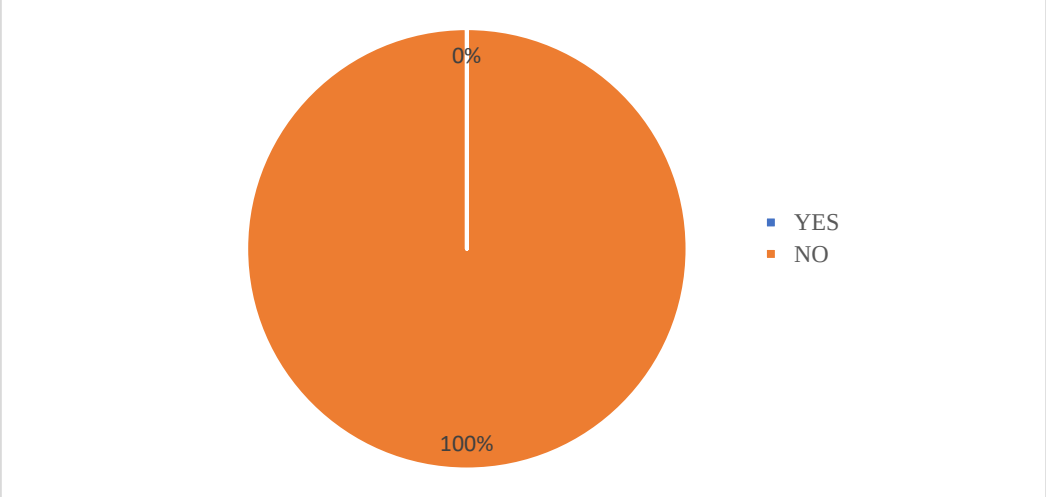
WOUND COMPLICATION

No wound complication was seen in any of the subjects at the end of 3 months follow up.

Table 10: Wound Complication

Wound Complication	70 Subjects
Yes	0%
No	100%

Figure 9: Wound Complication



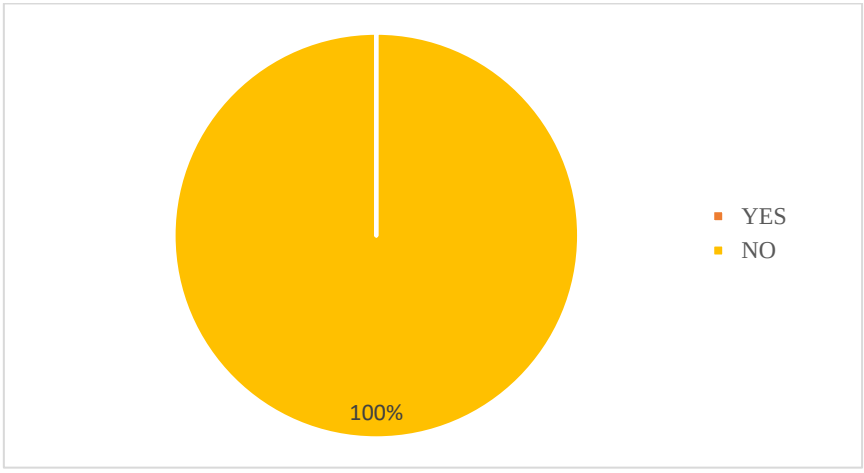
ADVERSE EVENTS (AE) OR SEVERE ADVERSE EVENTS (SAE):

In all the cases of clinical application in different surgical sites, there were no adverse events or severe adverse events reported on the day of operation or surgery and at 3 months follow up.

Table 11: Adverse Reaction

Adverse Reaction	70 Subjects
Yes	0%
No	100%

Figure 10:Adverse reaction



All the original tensile strength is lost by 21 days post implantation. Absorption of ADVAMRYL is essentially complete up to 90 days.

Table 12: Tensile strength of Poliglecaprone 25 suture

Day of Implantation	Approximate % original strength remaining	
	DYED	UNDYED
7 days	60%	55%
14 days	40%	20%

LIMITATIONS

PMCF studies can suffer from limitations like limited data and subject selection bias. Best efforts to overcome these limitations were made by collecting sufficient data from an extremely high number of surgical centres across a wide geography and surgical specialties, by maintaining a high rate of follow-up data collection and analysing data with a very high standard of accuracy.

CONCLUSION

- In this real-world experience study in 70 subjects, ADVAMRYL (Poliglecaprone 25) monofilament, synthetic absorbable sterile surgical sutures are used in a variety of surgical procedures. Follow-up data was obtained with a high rate of completion and high degree of accuracy.
- The study included subjects' data from >60 surgical centers across 13 different states of India, and included usage across 5 different surgical specialties, which demonstrates the wide diversity of clinical use of ADVAMRYL (Poliglecaprone 25) sutures.
- The study successfully achieved its primary and secondary safety and performance objectives, over a significantly long 3-month follow-up period.
- ADVAMRYL demonstrated excellent suture, needle and overall performance and were consistently rated excellent in surgeon's feedback across surgical specialties.
- No wound complications or adverse events were reported in this study during the follow-up period of 3 months, and there were no reports of prolonged or repeat hospitalization.
- ADVAMRYL (Poliglecaprone 25) sutures are a safe and effective option for a very wide variety of surgical procedures in a diverse population.

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Financial Disclosure statement
The study was sponsored by Advanced MedTech Solutions Pvt Ltd., Gujarat, India. No Financial remuneration or other benefits were paid to the hospitals or doctors contributing the subjects' data. The authors are full-time employees of Advanced MedTech Solutions Pvt. Ltd.

Conflict of Interest
No conflict of interest of any of the parties. Source documents can be made available on request.

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